REMARKS

The Office Action dated January 3, 2007 has been received and carefully noted. Claims 19-22, 24, 26-28, 30-59, 61-65, 67, 74 and 75 were examined. Claims 19-22, 24, 26-28, 30-59, 61-65, 67, 74 and 75 were rejected. Claims 19, 21, 24, 26-28, 30-44, 46-48, 51-54, 57-59, 61-62, 64 and 67 are amended. Support for the amendments can be found in, for example, page 18, lines 6-21 through page 19, line 1 and Figures 5A-5B of the Application. As such, no new matter has been added. Reconsideration of the pending claims is requested in view of the above-amendments and following remarks.

Although not required, a clean version of the amended claims is enclosed for the Examiner' s convenience.

I. Claims Rejected Under 35 U.S.C. § 112

A. Enablement Requirement

The Examiner has rejected Claims 24, 28, 33, 35, 38- 41, 44, 48, 54 and 63 under 35 U.S.C. §112, first paragraph, for failing, according to the Examiner, to meet the requirement of enablement. Applicants respectfully disagree. On September 4, 2001, Applicants filed the above-referenced Application as a divisional of Application Serial No. 08/644,101 and included the attached Preliminary Amendment, which changes were apparently not incorporated in the subsequently published application of the above-referenced Application, i.e., U.S. Pub. No 2002/0065448. Among other revisions, the Preliminary Amendment included the following insertions:

In the Specification:

FIG. 5A is a plan view of a centering balloon according to the present invention; and

FIG. 5B is a perspective sectional view of the centering balloon of FIG. 5A taken at line 5-5.

and

Page 18, line 8, after "balloon" insert – 60 (**FIG. 5A**)--;

line 11, correct spelling of –actually--;

line 13, after the first occurrence of "channel" insert –54--; same line, after the second occurrence of "channel insert –58--; same line, after the third occurrence of "channel" insert –56--;

line 14, after "balloon" insert –(**FIG. 5B**)--.

(Preliminary Amendment, pp.2-3). Thus, paragraph [0053] of U.S. Pub. No 2002/0065448 should properly read:

> [0053] In the preferred embodiment, an inflatable balloon 60 (**FIG. 5A**) is provided in the catheter for centering the source tip of the source wire. A dose of 1,000 to 1,500 rads drops off according to the inverse square of the distance, so that a distance of 5 mm from the vessel wall to the source (actually the tip of the source wire), causes the field strength to drop off sharply, with concomitant loss of threshold. The treatment catheter may include, in addition to the working treatment (radiotherapy) channel 54, the rail (guidewire) channel 58, an inflation channel 56 for the centering balloon (**FIG. 5B**). Segmented or scalloped balloons, or otherwise channeled balloons may be used, together with a channeled catheter or alone, to permit some flow-by of blood sufficient to avoid complete blockage during treatment.

(U.S. Pub. No 2002/0065448, revisions of Preliminary Amendment included). Thus, paragraph [0053] of the Published Application in combination with the description of the balloon 60 of Figures 5A and 5B in the Summary of Drawings as a "centering balloon" reasonably provides enablement for the longitudinally channeled, fluted, segmented or scalloped balloon being the means for centering. As such, Applicants request withdrawal of the rejection under 35 U.S.C. §112, first paragraph.

B. Written Description Requirement

Claims 28, 33, 38, 40, 44, 48, 54, 64-65, 67 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Claims 28, 33, 38, 40, 44, 48, 54, 64-65 and 67 include the limitation of "without dilating the lumen (or the duct or the vessel or said/the target site)." Although not explicitly disclosed in the specification, this function is an inherent feature of the segmented, scalloped, channeled or fluted balloon as

disclosed in the subject claims. By disclosing in a patent application a device that inherently performs a function or has a property, operates according to a theory or has an advantage, a patent application necessarily discloses that function, theory or advantage without introducing prohibited new matter. MPEP § 2163.07(a). The balloon disclosed in the specification includes inherent characteristics that prevent it from dilating a vessel wall. First, the balloon has less surface area with which to contact the wall of a vessel. That is, the balloon will only contact the vessel wall or the lesion at the lobed portions while allowing perfusion of blood flow between the lobed portions. Second, once a lobed portion of the balloon makes contact with the vessel wall or lesion, that portion will stop inflating due to the resistance exerted by the vessel wall or lesion while the remaining lobes will continue to inflate due to the lack of pressure, i.e., no contact with the vessel wall or lesion, on the remaining lobes. As a result, the balloon becomes centered and does not dilate the vessel wall. In view of these inherent characteristics of the balloon, Applicants respectfully request withdrawal of the rejection.

II. Claims Rejected Under 35 U.S.C. § 103

A. Claims Rejected as Unpatentable over *Weikl* in view of *Blackshear*

Claims 28, 30-41, 44-45, 47, 54, 59 and 67 were rejected under 35 U.S.C. 103(a) as being unpatentable over German Patent No. G 9,102,312.2 to Weikl ("*Weikl*") in view of U.S. Patent No. 5,308,356 to Blackshear, Jr. et al. ("*Blackshear*"). In order to establish a *prima facie* case of obviousness: (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference; (2) there must be a reasonable expectation of success; and (3) the references when combined must teach or suggest all of the claim limitations. MPEP § 2142. Applicants respectfully submit that a *prima facie* case of obviousness has not been established.

More specifically, the cited references do not teach or suggest all of the claim limitations of independent claims 28, 33, 38, 40, 44, 54 and 67. Amended independent claim 28 includes the limitation of "***radially centering a radiotherapy lumen . . . by inflating the balloon***." (App., claim 28) Amended independent claim 33 includes the limitation of "***wherein the centering device centers the radioactive material***." (App., claim 33) Amended independent claim 38

includes the limitation of "***centering source material . . . by inflating a centering device***." (App., claim 38) Amended independent claim 40 includes the limitation of "***radially centering source material . . . by inflating a centering device***." (App., claim 40) Amended independent claim 44 includes the limitation of "***radially centering a centering catheter by inserting into the lumen of the vessel the centering catheter wherein the centering catheter includes a distal portion of its length sized and shaped to substantially radially center a lumen within the catheter***." (App., claim 44) Amended independent claim 54 includes the limitation of "inflating the centering balloon through an inflation lumen of the radiation catheter ***wherein inflating the centering balloon substantially radially centers the radiotherapy lumen of the radiation catheter***." (App., claim 54) Amended independent claim 67 includes the limitation of "***deploying the centering device of the catheter . . . to substantially radially center the radiotherapy lumen of the catheter in the lumen of the duct at the site***." (App., claim 67) Representatively, the Application teaches that "an inflatable balloon 6 (FIG. 5A) is provided in the catheter for centering the source tip of the source wire." (App., p.18, lns. 6-7) Since the radioactive material is within a source wire, and the source wire is fed through the treatment channel 54 of catheter 12 (*see* App., FIG. 5B), centering treatment channel 54 (i.e., radiotherapy lumen) inherently centers the source wire having the radioactive material therein and, thereby, centering the radioactive material. (*see* App., FIG. 5B)

By contrast, *Weikl* teaches a device for the dilation of a blood vessel occlusion using a treatment catheter with a balloon attached to the tip wherein a circumference of the balloon can undergo a definite expansion. (*Weikl*, p. 2) In order to achieve a better centering of radiation source 16 within the lumen of treatment catheter 1, *Weikl* teaches that treatment catheter 1 can be equipped with a central or approximately central supply duct 21. (*Weikl*, p.7) According to *Weikl*, the central supply duct 21 may be in a fixed position within lumen 24 of treatment catheter 1 by means of longitudinal intermediate walls 22 and 23. (*Weikl*, p.7; FIG. 2b) Contrary to the claimed invention, *Weikl* does not teach or suggest that balloon 4 of treatment catheter 1 can provide centering means to center radiation source 16, but instead only teaches an embodiment in which a central supply duct 21 is "fixed" to provide centering thereof. Thus, *Weikl* does not teach or suggest all of the limitations of the rejected independent claims, namely, the limitations discussed in more detail previously. *Blackshear* does not cure this lack of teaching or suggestion because *Blackshear* teaches a passive perfusion angioplasty catheter which includes an inflated

balloon member affixed to a distal end of an elongated flexible member. (*Blackshear*, Abstract) *Blackshear* teaches that balloon member 16 has a pleated design with helical groves. (*Blackshear*, col.6, ln. 22; FIGs. 1, 3, 6, 8-11, 15, 16c) The Examiner has not relied upon and Applicants have been unable to discern any part of *Blackshear* that teaches or suggests the limitations recited in the rejected independent claims, namely, the limitations discussed in more detail previously. Dependent claims 30-32, 34-37, 39, 41-43, 46-47 and 55-59 depend on the independent claims 28, 33, 38, 40, 44, 54 and 67, respectively, and therefore include all of the limitations thereof.

Moreover, Applicants respectfully disagree with the Examiner' s characterization that *Weikl* teaches "inflating the balloon to substantially center the radiotherapy lumen (Figure 2)." (Office Action, p.3) Instead, *Weikl* teaches that its radioactive source 16 is centered by a ***fixed*** lumen 24. (*Weikl*, p.7; FIG. 2b) Thus, neither *Weikl* nor *Blackshear* (as discussed previously) teach or suggest the limitation cited by the Examiner in the Office Action and included in the rejected claims.

Additionally, Applicants contend that there is no motivation to combine *Weikl* with *Blackshear* to arrive at Applicants' claimed invention. The mere fact that references can be combined does not render the resultant combination obvious unless the prior art also suggest the desirability of the combination. MPEP § 2143.01(III). Specifically, *Weikl* teaches a means for centering radiation source 16 by describing a fixed lumen 24 within treatment catheter 1. (*Weikl*, p.7; FIG. 2b) One of ordinary skill in the art would not be motivated to look toward *Blackshear* to teach an alternative means for performing the same function, i.e., centering a radiation source by including a fixed center lumen in a treatment catheter, since there is no teaching or suggestion in either *Weikl* or *Blackshear* that *Weikl's* means is inadequate for the purposes disclosed in *Weikl*. Thus, one of ordinary skill in the art, at the time the invention is claimed, would not be motivated to combine *Weikl* with *Blackshear* to arrive at Applicants' claimed invention.

In view of the remarks above, Applicants submit that the rejected independent claims and their respective dependent claims are allowable over the cited references.

B. Claims Rejected as Unpatentable over *Weikl* in view of *Blackshear* and further in view of *Van't Hooft*

Claims 48, 51-53, and 57-58 were rejected under 35 U.S.C. 103(a) as being unpatentable over *Weikl* in view *Blackshear* and further in view of U.S. Patent No. 4,881,937 to Van' t Hooft et al. ("*Van't Hooft*"). Applicants submit that the combined references do not teach or suggest all of the claim limitations of independent claims 48 and 58.

Independent claim 48 includes the limitation of "***inflating the balloon to substantially align a radiotherapy lumen of the catheter with the longitudinal axis of the coronary artery at the target site***." (App., claim 48) Amended independent claim 54 includes the limitation of "inflating the centering balloon through an inflation lumen of the radiation catheter ***wherein inflating the centering balloon substantially radially centers the radiotherapy lumen of the radiation catheter***." (App., claim 54) *Weikl* combined with *Blackshear* does not teach or suggest this limitation as discussed in detail in section II(A) of this Response. *Van't Hooft* does not cure this lack of teaching or suggestion because *Van't Hooft* describes moving a dummy wire to a target site within an organ, checking its position by means of an X-ray image intensifier and then moving a radioactive material to the target site. (col. 1, lns. 54-58) Thus, the combined references do not teach or suggest all of the limitations recited in claims 48 and 58.

Moreover, even assuming *arguendo* that the combined references teach or suggest all of the claim limitations, there is no motivation to combine the references to arrive at Applicants' claimed invention. To that end, the Examiner has failed to provide one. (*see* Office Action, p.4) The mere fact that references can be combined does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. MPEP § 2143.01(III). *Weikl* describes a treatment catheter 1 which can be used to deliver radiation source 16 to treat a stenosis within a blood vessel. (*Weikl*, p.7) According to *Weikl*, "[t]he position of the radiation source 16 can be established at any time with precision, and its position can be observed, for example, on a screen." (*Id.*) *Blackshear* describes a passive perfusion angioplasty catheter which includes an inflated balloon member affixed to a distal end of an elongated flexible member to treat a stenosis within a blood vessel. (*Blackshear*, Abstract) *Van't Hooft*, on the other hand, describes moving a dummy wire to a target site within an organ, checking its position by means of an X-ray image intensifier, and then moving a radioactive material to the target site. (col. 1,

lns. 54-58) As one of ordinary skill in the art would appreciate, accurately locating a treatment site within an ***organ*** is much different than locating a treatment site within a ***blood vessel***. It seems that locating a treatment site within a lung, as taught and illustrated in *Van't Hooft*, allows much more room for error versus locating a constricted portion of a blood vessel using conventional methods in angioplastic procedures. Thus, one of ordinary skill in the art would not be motivated to look toward *Blackshear* to teach an alternative means for performing the same function, i.e., precisely locating a radiation source during treatment, since there is no teaching or suggestion in either *Weikl* or *Blackshear* that the means disclosed in the *Weikl* and *Blackshear* are inadequate for their intended purposes. Therefore, one of ordinary skill in the art, at the time the invention is claimed, would not be motivated to combine either *Weikl* or *Blackshear* with *Van't Hooft* to arrive at Applicants' claimed invention.

Dependent claims 49-53 and 55-59 depend on independent claims 48 and 54, respectively, and therefore include all of the limitations thereof. In view of the remarks above, Applicants submit that the rejected claims are allowable over the cited references.

C. Claims Rejected as Unpatentable over *Weikl* in view of *Malinowski*

Claim 61 was rejected under 35 U.S.C. 103(a) as being unpatentable over *Weikl* in view of U.S. Patent No. 5,660,180 to Malinowski et al. ("*Malinowski*"). Applicants submit that the combined references do not teach or suggest all of the claim limitations of independent claim 61.

Independent claim 61 includes the limitation of "***using a centering catheter having an inflatable centering balloon with channels for enabling . . . the radial centering of the inflatable centering balloon***." (App., claim 61) *Weikl* does not teach or suggest this limitation as discussed in detail in section II(A) of this Response. *Malinowski* does not cure this lack of teaching or suggestion because *Malinowski* describes an ultrasonic imaging guidewire apparatus. (*Malinowski*, Abstract) Thus, the combined references do not teach or suggest all of the limitations recited in claim 61.

Moreover, even assuming *arguendo* that the combined references teach or suggest all of the claim limitations, there is no motivation to combine the references to arrive at Applicants'

claimed invention. To that end, the Examiner has failed to provide one other than stating that "the use of guidewires to aid in inserting catheters is well known." (*see* Office Action, p.5, ¶ 8) A statement that modifications of the prior art to meet the claimed invention would have been well within the ordinary skill of the art at the time the claimed invention was made because the references relied upon teach all aspects of the claimed invention were individually known in the art is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the reference. MPEP § 2143.03(IV).

In view of the remarks above, Applicants submit that the claim 61 is allowable over the cited references.

D. Claims Rejected as Unpatentable over *Weikl* in view of *Malinowski* and further in view of *Blackshear*

Claims 19, 21-22, 24, 27, 62-65 and 74-75 were rejected under 35 U.S.C. 103(a) as being unpatentable over *Weikl* in view of *Malinowski* and further in view of *Blackshear*. Applicants submit that the combined references do not teach or suggest all of the claim limitations of independent claims 61, 74 and 75. Independent claim 61 includes the limitation of "***using a centering catheter having an inflatable centering balloon with channels for enabling . . . the radial centering of the inflatable centering balloon***." (App., claim 61) Independent claim 74 includes the limitation of "***inflating the balloon to substantially center the catheter radiotherapy lumen*** within the vessel lumen at the target site." (App., claim 74) Independent claim 75 includes the limitation of "***deploying the centering device of the catheter to position a radiotherapy lumen of the catheter at substantially the radial center of the lumen*** of the duct at the site." (App., claim 75) None of the cited references teach or suggest these limitations as discussed previously in detail in sections II(A) and III(C) of this Response.

Moreover, even assuming *arguendo* that the combined references teach or suggest all of the claim limitations, there is no motivation to combine the references to arrive at Applicants' claimed invention. To that end, the Examiner has failed to provide one. (*see* Office Action, p.5, ¶ 9) Applicants respectfully remind the Examiner that a statement that modifications of the prior art to meet the claimed invention would have been well within the ordinary skill of the art at the time the claimed invention was made because the references relied upon teach all aspects of the

claimed invention were individually known in the art is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the reference. MPEP § 2143.03(IV).

Dependent claims 62, 19-22, 64, 24, 26-27 and 65 depend on independent claims 61, 74 and 75, respectively, and therefore include all of the limitations thereof. In view of the remarks above, Applicants submit that the rejected claims are allowable over the cited references.

E. Claims Rejected as Unpatentable over *Weikl* in view of *Malinowski* and *Blackshear* and further in view of Flexmedic article

Claims 20, 26, 42-43, 46, 49-50 and 55-56 were rejected under 35 U.S.C. 103(a) as being unpatentable over *Weikl* in view of *Malinowski* and *Blackshear* further in view of the Flexmedic article. Applicants submit that the combined references do not teach or suggest all of the claim limitations of the independent claims on which the rejected dependent claims depend for the reasons stated in sections II(A) and III(A)-(D) of this Response. The Flexmedic article does not cure this lack of teaching or suggestion because the Flexmedic article is only directed to the use of Nitinol in medical applications.

Dependent claims 20, 26, 42-43, 46, 49-50 and 55-56 depend on independent claims on which the dependent claims depend and therefore include all of the limitations thereof. In view of the remarks above, Applicants submit that the rejected claims are allowable over the cited references.

CONCLUSION

In view of the foregoing, it is believed that all claims now pending are in condition for allowance and such action is earnestly solicited at the earliest possible date. If the Examiner believes that a telephone conference would be useful in moving the application forward to allowance, the Examiner is encouraged to contact the undersigned at (310) 500-4787.

Respectfully submitted,

BLAKELY, SOKOLOFF, TAYLOR & ZAFMAN, LLP

Dated: April 18, 2007

Shelley M. Cobos Reg. No. 56,174

12400 Wilshire Boulevard
Seventh Floor
Los Angeles, California 90025
Telephone (310) 207-3800
Facsimile (310) 820-5988

CERTIFICATE OF TRANSMISSION

I hereby certify that this correspondence is being submitted electronically via EFS Web to the United States Patent and Trademark Office on April 18, 2007.

Si Vuong